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# Less May Be More: Reading into FDA's Labeling Requirements

Diana R. H. Winters\*

Last year the Food and Drug Administration (FDA) announced several actions designed to improve the quality of information provided to consumers on food labels.<sup>1</sup> These include an update to the nutrition facts panel—the table containing quantities of calories and certain designated nutrients that appears on most packaged food.<sup>2</sup> The FDA is also asking for comment regarding whether the agency should define the term “natural”<sup>3</sup> and redefine the term “healthy” for use on food labels.<sup>4</sup> While the former will make needed and useful changes to food labels, the quest to further pin down definitions for words such as “healthy” and “natural” will not result in any improvement to our nation’s food supply, and the resources needed to take these actions are better spent elsewhere.<sup>5</sup>

Defining and enforcing the parameters of permissible and mandated information disclosure is one of the primary regulatory mechanisms we use to monitor and improve our food systems. The Food, Drug, and Cosmetic Act (FDCA)<sup>6</sup> and the Nutrition Labeling and Education Act (NLEA)<sup>7</sup> require accurate and relevant nutritional information on food products so that consum-

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\* Associate Professor, Indiana University Robert H. McKinney School of Law. Many thanks to Nathan Cortez, Joanna Sax, Neil Fortin, and all of the participants at the 2016 Texas Food Law Forum held at Southern Methodist University in collaboration with Michigan State University’s Institute for Food Laws and Regulations, the SMU Science and Technology Law Review, and the Food & Drug practice group at Strasburger & Price.

1. *Changes to the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN. (Nov. 22, 2016), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm>.

2. *Id.*

3. “*Natural*” on Food Labeling, U.S. FOOD & DRUG ADMIN. (Sept. 14, 2016), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm>.

4. *FDA to Redefine “Healthy” Claim for Food Labeling*, U.S. FOOD & DRUG ADMIN. (Dec. 29, 2016), <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm520703.htm>.

5. This article expands on a blog post the author wrote for the Health Affairs blog. See Diana Winters, *Are the FDA’s New Definitions and Labeling Requirements Good for Us, or Just Empty Calories*, HEALTH AFFAIRS BLOG (June 24, 2016), <http://healthaffairs.org/blog/2016/06/24/are-the-fdas-new-definitions-and-labeling-requirements-good-for-us-or-just-empty-calories/>.

6. This article expands on a blog post the author wrote for the Health Affairs blog. See Diana Winters, *Are the FDA’s New Definitions and Labeling Requirements Good for Us, or Just Empty Calories*, HEALTH AFFAIRS BLOG (June 24, 2016), <http://healthaffairs.org/blog/2016/06/24/are-the-fdas-new-definitions-and-labeling-requirements-good-for-us-or-just-empty-calories/>.

ers may make informed decisions and to promote a more competitive marketplace. But disclosure requirements can only effect meaningful change if narrowly crafted to achieve precise objectives; the FDA has so far failed to articulate these specific goals. In fact, it is unclear whether we, as a society, can even articulate these goals.

Take, for example, the new federal law passed requiring the labeling of foods containing genetically modified ingredients.<sup>8</sup> The purpose of this law was to preempt the passage of stricter state laws and to provide consumers with information they purport to want (polls have found that the majority of consumers support the mandatory labeling of foods containing genetically modified organisms (GMOs)).<sup>9</sup> The law accomplishes both. But the law falls short to provide consumers with the information that they actually seek about the GMO ingredients—whether food products containing them are less safe than conventional foods.<sup>10</sup>

Determining whether one ingredient is safer than another is complex regardless of whether or not an ingredient is genetically modified. In addition to the scientific uncertainty of which ingredients are considered “safe,” effectively defining the term “safe” to match the wide variance among consumer expectations can prove even more difficult. Then, once accurately defined, it may be impossible to clearly communicate an overall metric of “safety” on a food label. Accordingly, under a false sense of making an informed decision, consumers who believe that GMOs are less safe than non-GMO ingredients may be misled by these labels, spending more money for food that is actually no safer. The GMO labeling law provides consumers with information they think they want, but not the information they need, and in doing so may alter consumer preference based on false assumptions.<sup>11</sup> Worse, the GMO labeling law utilizes scarce industry and agency resources for implementation and enforcement. The labeling requirement is just one example of how the failure to articulate specific goals before mandating disclosure can be harmful.

Because of a shift in resources and priorities under the Trump administration, it is uncertain whether the (re)definitions of “healthy” and “natural”

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7. Nutrition Labeling and Education Act of 1990, Pub. L. 101-535, 104 Stat. 2353.

8. *Changes to the Nutrition Facts Label*, *supra* note 1.

9. See, e.g., Gary Langer, *Poll: Skepticism of Genetically Modified Foods*, ABC News (June 19, 2016) (poll shows that 93% of consumers want GMO labeling), <http://abcnews.go.com/Technology/story?id=97567&page=1>. But see William Saletan, *Unhealthy Fixation*, SLATE (July 15, 2015) [http://www.slate.com/articles/health\\_and\\_science/science/2015/07/are\\_gmos\\_safe\\_yes\\_the\\_case\\_against\\_them\\_is\\_full\\_of\\_fraud\\_lies\\_and\\_errors.html](http://www.slate.com/articles/health_and_science/science/2015/07/are_gmos_safe_yes_the_case_against_them_is_full_of_fraud_lies_and_errors.html) (arguing that “[t]he war against genetically modified organisms is full of fearmongering, errors, and fraud. Labeling them will not make you safer.”).

10. See Saletan, *supra* note 9.

11. *Id.*

and the continued implementation of the rewritten nutrition facts label will progress under the Trump administration.<sup>12</sup> Nevertheless, it is worthwhile to consider the role and goals of the regulation of disclosure in the context of food labels for future regulatory efforts. This paper discusses these three FDA initiatives and explores the role of disclosures as a regulatory technique. It then proposes several solutions for the disconnect between required disclosures and targeted objectives.

### I. The Regulatory Background

In 1990, Congress passed the NLEA, which required the FDA to standardize and regulate the “nutrient content claims” and “health claims” of food labels.<sup>13</sup> In the early 1990s, the FDA issued regulations pursuant to this mandate, explaining that a *nutrient content claim* is “[a] claim that expressly or implicitly characterizes the level of a nutrient” in food—like “low fat” or “high in bran.”<sup>14</sup> And a *health claim* “characterizes the relationship of any substance to a disease or health-related condition,”<sup>15</sup>—e.g., X may “reduce the risk of heart disease.”<sup>16</sup> Implied nutrient content claims include claims that “the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient.”<sup>17</sup> Food labels can only contain the word “healthy” if the food meets certain conditions as to the amount of fat, saturated fat, cholesterol, and other nutrients, as explained in the regulations.<sup>18</sup>

Although the understanding of how fat affects the body has changed over the last few decades,<sup>19</sup> the FDA has not updated the regulation detailing the parameter of the term “healthy” since it was issued in the early 1990s.<sup>20</sup> This became an issue in 2015 when the FDA notified the Chief Executive

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12. See Josh Blackman, *Unraveling Obama-Era Regulations on Day One with the Congressional Review Act*, JOSH BLACKMAN'S BLOG (Nov. 22, 2016), <http://joshblackman.com/blog/2016/11/22/unraveling-obama-era-regulations-on-day-one-with-the-congressional-review-act/> (identifying revision of the nutrition facts label as subject to reversal under the Congressional Review Act).
  13. See *Nutritional Labeling and Education Act (NLEA) Requirements* (8/94 – 2/95), U.S. FOOD & DRUG ADMINISTRATION (Nov. 25, 2014), <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>.
  14. Nutrient Content Claims, 21 C.F.R. § 101.13(b) (2016).
  15. Health Claims, 21 C.F.R. § 101.14(a)(1) (2016).
  16. See, e.g., 21 C.F.R. §§ 101.75(c)(2), 101.81(c)(2).
  17. 21 C.F.R. § 101.13(b)(2)(ii).
  18. 21 C.F.R. § 101.65(d)(2).
  19. See, e.g., Jane Brody, *What's New in the Dietary Guidelines*, N.Y. TIMES (Jan. 18, 2016), [http://well.blogs.nytimes.com/2016/01/18/whats-new-in-the-dietary-guidelines/?\\_r=0](http://well.blogs.nytimes.com/2016/01/18/whats-new-in-the-dietary-guidelines/?_r=0).
  20. 21 C.F.R. § 101.65(d)(2).

Officer at Kind, LLC, a company that manufactures protein bars, that the company was misusing the term “healthy” because the bars contained more saturated fat than was allowed under the regulations.<sup>21</sup> The company responded that the fat in its bars was derived from nuts, which are “generally considered to be good for you.”<sup>22</sup> The media extensively covered the dispute, which focused on the perceived selective targeting of this company and the absurdity of the agency’s stance on saturated fat.<sup>23</sup> The FDA backed down in mid-2016, letting the company use the term “‘healthy and tasty’ only in text clearly presented as its corporate philosophy, where it isn’t represented as a nutrient content claim,” and stating that it planned to ask for public comment soon on the question of how “healthy” should be defined.<sup>24</sup> In September 2016, the agency issued a call for public comment on redefining the term.<sup>25</sup>

The FDA has repeatedly declined to define the term “natural.”<sup>26</sup> In 1991, as it was working on its NLEA regulations, the FDA solicited public comment on a definition, stating that “if the term ‘natural’ is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated.”<sup>27</sup> The agency did not, however, define the term, citing “resource limitations and other agency priorities,”<sup>28</sup> and explained that it would “maintain its policy . . . regarding the use of ‘natural,’ as meaning

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21. *KIND, LLC 3/17/15 – Warning Letter*, U.S. FOOD & DRUG ADMIN. (Mar. 17, 2015), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm440942.htm>.
  22. *A Letter to our Fans: KIND and Nutrition Policy—Sparking a Healthy Discussion*, KIND LLC (Dec. 1, 2015), <https://www.kindsnacks.com/blog/post/a-letter-to-our-fans-kind-and-nutrition-policy-sparking-a-healthy-discussion/>.
  23. See, e.g., Poncie Rutsch, *Nut So Fast, Kind Bars: FDA Smacks Snacks on Health Claims*, NPR (Apr. 15, 2015, 6:37 PM ET), <http://www.npr.org/sections/thesalt/2015/04/15/399851645/nut-so-fast-kind-bars-fda-smacks-snacks-on-health-claims>; see also Anna Almendrala, *Why The FDA Action Against KIND Bars Doesn’t Mean They’re Unhealthy*, THE HUFFINGTON POST (Apr. 15, 2015), [http://www.huffingtonpost.com/2015/04/14/fda-kind-bars\\_n\\_7066704.html](http://www.huffingtonpost.com/2015/04/14/fda-kind-bars_n_7066704.html).
  24. *Statement on FDA’s Actions on Labeling of KIND Products*, U.S. FOOD & DRUG ADMIN. (May 10, 2016), <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm500184.htm>.
  25. *“Healthy” on Food Labeling*, U.S. FOOD & DRUG ADMIN. (Sept. 28, 2016), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm520695.htm>.
  26. *What is the meaning of ‘natural’ on the label of food?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/transparency/basics/ucm214868.htm> (last updated Jan. 1, 2017).
  27. *Terms that Describe Other Aspects of Food*, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5 & 101).
  28. *Id.*

that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.”<sup>29</sup> In 2013, after a wave of litigation against food manufacturers regarding their use of “natural” on food labels, several courts stayed these suits pending the agency’s determination.<sup>30</sup> In a letter to these courts the agency again declined to define the term, citing resource limitations.<sup>31</sup> In late 2015, however, the FDA again requested public comment on the issue, and it received close to 8,000 comments before the comment period closed in May 2016.<sup>32</sup>

The nutrition facts panel implements the NLEA’s requirement that food labels contain nutrition information.<sup>33</sup> This highly recognizable table on most packaged foods contains calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, and various vitamins and minerals.<sup>34</sup> In 2014, the FDA proposed a rule updating this label, which was finalized in mid-2016.<sup>35</sup> The new label will update serving sizes to better reflect what Americans are actually eating, change the required nutrient listings, and require manufacturers to list added sugars in addition to total sugars.<sup>36</sup>

These three FDA initiatives—the definition of “natural,” the redefinition of “healthy,” and the redesign of the nutrition facts panel—are new agency actions in various stages of completion.<sup>37</sup> As the Trump administration takes power, changed priorities may mean that the FDA turns its attention away from these initiatives. I expect this to happen with the definitions of “healthy” and “natural”—an administration interested in cutting regulation will most likely be reluctant to expend resources on tweaking such regula-

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29. *Id.*

30. Diana R. H. Winters, *Restoring the Primary Jurisdiction Doctrine* (Indiana Univ. Robert H. McKinney School of Law Research Paper No. 2016-16, 2016), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2746200##](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2746200##).

31. Letter from Leslie Kux, Assistant Comm’r for Policy, to The Honorable Yvonne Gonzales Rogers, N.D. Cal., The Honorable Jeffrey S. White, N.D. Cal., and The Honorable Kevin McNulty, D.N.J. (Jan. 6, 2014), <http://files.dlapiper.com/files/upload/FDA-Letter-to-Judges-Declining-Natural-1-6-13.pdf>.

32. “*Natural*” on Food Labeling, *supra* note 3.

33. Misbranded Food, 21 U.S.C. § 343(q)(1) (2010).

34. 21 C.F.R. § 101.9(c).

35. *See Changes to the Nutrition Facts Label*, *supra* note 1; *see also* Press Release, FDA Revises Proposed Nutrition Facts Label Rule to Include a Daily Value for Added Sugars, U.S. Food & Drug Admin. (Jul. 24, 2015), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455837.htm>.

36. *Changes to the Nutrition Facts Label*, *supra* note 1.

37. *Id.*

tion, especially in an area (defining “natural”) that the agency has been ambivalent about for decades. As long as the regulations contain a definition of “healthy,” it makes sense for this definition to comport with modern scientific understanding, but the FDA has promised not to pursue violators under certain conditions in any event.<sup>38</sup> The rule updating the nutrition facts panel has already been issued and is thus more likely to move forward.<sup>39</sup> The requirement that food manufacturers disclose added sugars was very controversial and may put this new rule at risk.<sup>40</sup> But regardless of whether the new administration pursues these specific initiatives, this is a good time to step back and think about the role and usefulness of mandatory disclosure as a regulatory strategy in regards to food policy.<sup>41</sup>

## II. Information Disclosure as Regulation

Regulating information with mandated disclosure is an extremely popular regulatory technique. Mandated disclosure is a “standard—one might almost say favored—weapon in the arsenals of legislatures, courts, administrative agencies, and commentators.”<sup>42</sup> This is so for several reasons. First, because the provision of more information to consumers tends to garner broad support.<sup>43</sup> Transparency is an easy value to get behind.<sup>44</sup> Second, mandatory disclosure is a relatively inexpensive regulatory technique.<sup>45</sup> Reformulating labels costs less than reformulating a product to comply with more stringent regulation.<sup>46</sup> Lastly, disclosure laws can displace more stringent regulation, both through explicit preemption (i.e. the federal GMO la-

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38. *Guidance for Industry: Use of the Term “Healthy” in the Labeling of Human Food Products*, U.S. FOOD & DRUG ADMIN. (Sept. 2016), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm521690.htm> (explaining that the agency would exercise enforcement discretion if a product is “not low in total fat, but ha[s] a fat profile makeup of predominantly mono and polyunsaturated fats,” among other things).

39. FDA Revises Proposed Nutrition Facts Label Rule, *supra* note 35.

40. *Id.*

41. The author refers to the agency’s requirements for nutrient content and health claims as mandatory disclosure because even though no food manufacturer is required to use these terms, they must comply with certain requirements if they do choose to use them.

42. Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PENN. L. REV. 647, 652 (2011).

43. *See id.* at 681–82.

44. *See, e.g., id.* at 681–84.

45. *Id.* at 682.

46. *See id.* at 682, 739–40.

beling law preempts stricter state regulation), and by absorbing any political will for action.<sup>47</sup>

Mandated disclosure “address[es] a real problem,” and “rests on [the] plausible assumption . . . that when it comes to decisionmaking, more information is better than less.” But this regulatory technique “regularly fails in practice.”<sup>48</sup> In 2011, Omri Ben-Shahar and Carl E. Schneider wrote an article about this phenomenon, identifying various drivers behind the failure of mandated disclosure; they concluded that this failure may, in fact, be inevitable.<sup>49</sup> They point to the complexity of designing effective mandated disclosure as a major obstacle to its success, looking to the compounded shortcomings of legislators, disclosers, and consumers as factors in the technique’s failure.<sup>50</sup> Lawmakers must identify a problem, then determine that mandating disclosure will appropriately address the problem, then determine exactly what must be disclosed, and then properly articulate a standard.<sup>51</sup> Disclosers must determine precisely what to disclose, assemble the necessary data, and present the information effectively.<sup>52</sup> Consumers are often left to wade through so much information that it becomes impractical to understand, remember, or properly analyze.<sup>53</sup> Ben-Shahar and Schneider conclude that “[r]arely can each actor accomplish all that is needed, and therefore mandated disclosures rarely work as planned.”<sup>54</sup>

Ben-Shahar and Schneider comprehensively analyzed the failure of mandated disclosure, but such criticism is not new. Scholars have noted the complexity and precariousness of disclosure as a regulatory technique for decades. For example, in 1994, Lars Noah discussed the “preferred strategy” of legislators to use warning labels on consumer products carrying risk, and explained that decision-makers need to be more selective when choosing a regulatory strategy to deal with risk and to be more careful in the design of warnings if warnings are the chosen strategy.<sup>55</sup> He notes the “substantial costs associated with the overuse of warnings, particularly the twin dangers of diluting the impact of more serious warnings and prompting counter-

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47. See *id.* at 740; see also National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016).

48. Ben-Shahar & Schneider, *supra* note 42, at 650–51.

49. *Id.* at 651.

50. See, e.g., *id.* at 672–729.

51. *Id.* at 679.

52. *Id.* at 692, 695, 696.

53. *Id.* at 705, 711, 716, 719–20.

54. Ben-Shahar & Schneider, *supra* note 42, at 679.

55. Lars Noah, *The Imperative to Warn: Disentangling the ‘Right to Know’ from the ‘Need to Know’ about Consumer Product Hazards*, 11 YALE J. ON REG. 293, 295–98 (1994).



productive consumer behavior in response to overly alarming warnings about relatively insignificant risks.”<sup>56</sup>

In 1999, William Sage wrote about the use of the disclosure of health-care information as a regulatory strategy.<sup>57</sup> He discussed the popularity of mandatory disclosure laws, identified four rationales for disclosure laws in the healthcare context, and questioned how the implementation of disclosure laws satisfies these rationales.<sup>58</sup> He concluded that although disclosure is a very appealing regulatory technique, the blanket provision of information without a theoretical cohesiveness underlying the disclosure scheme is not always a good thing.<sup>59</sup> Information only has value if people can act on it, and only has meaning if there is a consensus as to the objectives and principles that underlie the specific context in which the disclosure is taking place.<sup>60</sup>

### III. Effective Food Labeling Disclosures

The FDA has been regulating food-labeling disclosures since its inception in the late 1930s, and with more focus and authority since the passage of the NLEA in 1990.<sup>61</sup> But before continuing to work within this disclosure framework and spending resources to incrementally tweak definitions within the existing framework, regulators should articulate the objectives underlying the food labeling disclosure scheme and analyze: (1) whether disclosure is the correct regulatory technique to achieve this objective; (2) what is the correct standard of disclosure; and (3) the feasibility of effective implementation, including consumer comprehension.<sup>62</sup>

As articulated in its 2014–2018 strategic priorities, an FDA objective is to advance food safety and nutrition.<sup>63</sup> The agency works to ensure “truthful and informative labeling on packaged and other foods,” so that “American consumers can use this information to make healthier choices about the food

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56. *Id.* at 296.

57. See William M. Sage, *Regulating Through Information Disclosure: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999).

58. See *id.* at 1710–11. (These four rationales are: the promotion of competition, the strengthening of agency relationships and the enforcement of fiduciary obligations, improving the performance of the system, and increasing public awareness and political accountability.).

59. See *id.* at 1826–27.

60. *Id.* at 1825–27.

61. *Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2014), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm>.

62. See, e.g., Sage, *supra* note 57, at 1727–28.

63. *Strategic Priorities: Strategic Goals and Long-Term Objectives*, U.S. FOOD & DRUG ADMIN. (Apr. 20, 2011), <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm246751.htm>.

they eat and help them reduce the risk of chronic disease and facilitate optimal health.”<sup>64</sup> Mandatory labels are tools to achieve improved health outcomes by assisting consumers in making good choices.<sup>65</sup> Along with other tools, such as the regulation of production practices and outright prohibitions, the FDA uses mandatory disclosures to ensure a safe, healthy, and accessible food supply for the American public.<sup>66</sup>

Consider the implications of what is known about the effectiveness of the nutrition facts panel. Studies have shown that consumers actually use the nutrition facts panel to make decisions about what foods to purchase and eat. A 2007–2008 FDA survey showed that thirty-four percent of respondents used the nutrition facts panel “always or most of the time”; by 2009–2010 the number increased to forty-two percent.<sup>67</sup> And evidence suggests that the use of the nutrition facts panel is associated with better health outcomes.<sup>68</sup> Moreover, food manufacturers have been using the nutrition facts panel for almost thirty years.<sup>69</sup> While the information on the panels is occasionally inaccurate, there has been no widespread reporting of mistakes or fraud on these labels.<sup>70</sup> In short, reliance is high, cost of continued compliance is low, and there is some evidence of effectiveness. It makes sense for the FDA to update the nutrition facts panel to better reflect the eating patterns and nutrient needs of American consumers.

Defining “healthy” and “natural” is a different story. As long as the FDA’s regulations contain a definition for “healthy,” that definition should reflect current scientific knowledge.<sup>71</sup> A better route, however, is for the agency to abandon this endeavor. But any definition of the words “natural”

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64. *Id.*

65. *Id.*

66. See Sage, *supra* note 57, at 1741, 1747–48.

67. Darlene Superville & Mary Clare Jalonick, *New Food Labels Aim to Make Healthy Shopping Easy*, ASSOCIATED PRESS ONLINE (Feb. 27, 2014, 10:35 PM), <http://www.houstonchronicle.com/news/nation-world/nation/article/New-food-labels-aim-to-make-healthy-shopping-easy-5274885.php>.

68. Cf., e.g., Grace Kollannoor-Samuel et al., *Nutrition Facts Panel use is Associated with Higher Diet Quality and Lower Glycated Hemoglobin Concentrations in US Adults with Undiagnosed Prediabetes*, 104 AM. J. CLINICAL NUTRITION 1639 (Oct. 26, 2016), <http://ajcn.nutrition.org/content/104/6/1639.abstract>.

69. *Significant Dates in U.S. Food and Drug Law History*, *supra* note 61.

70. See Tamara Duker Freuman, *When Nutrition Labels Lie*, U.S. NEWS & WORLD REPORT (Aug. 21, 2012, 12:50 PM), <http://health.usnews.com/health-news/blogs/eat-run/2012/08/21/when-nutrition-labels-lie>.

71. See *Use of the Term “Healthy” in the Labeling of Human Food Products: Guidance for Industry*, U.S. FOOD & DRUG ADMIN. (Sept. 2016), <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM521692.pdf>.

and “healthy” will almost certainly be more philosophical than scientific, and any agreed upon definition will represent a compromise among interested stakeholders.<sup>72</sup> Although one may argue that a food’s “healthfulness” should be an objective determination, any review of the disputes over the nutritional effects of sugar, or meat, or dairy, demonstrates that the word has many interpretations, and is infused with political and financial considerations. This is plainly apparent too in the thousands of comments submitted regarding the agency’s potential definition of “natural.”<sup>73</sup>

Still, whether scientific or not, some argue for defining “natural” and redefining “healthy” to level the playing field for food manufacturers. No longer will industry have to guess what consumers want by these words, nor whether they will be held liable for violating state fraudulent practices acts by misusing these words.<sup>74</sup> But this justification is a hollow support. Even though the FDA has historically used its labeling power to protect industry from economic fraud, this was always done while also helping the consumer.<sup>75</sup> If labels were standard, consumers would not be tempted by cheaper, but inferior goods represented as equal to or better than superior products.<sup>76</sup> Here both industry and consumers are protected. But negotiated and compromised definitions of “healthy” and “natural” will help industry, to the potential detriment of consumers. For example, if a negotiated definition of “natural” includes products that have been artificially manipulated (like high fructose corn syrup), consumers will have to be taught that “natural” does not mean “healthy,” nor does it actually mean “natural” in any intuitive sense of the word.<sup>77</sup>

#### IV. Solutions and Conclusion

The FDA has taken several steps toward improving the information that food manufacturers must provide to American consumers.<sup>78</sup> But more information is not always better. Unless we can articulate the specific objectives we are trying to achieve, tailor the regulation of information to these disclosures, effectively monitor the implementation of the regulation, and ensure that consumers properly understand the information they are given, the ma-

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72. See, e.g., Diana Winters, *Are The FDA’s New Definitions*, *supra* note 5.

73. *Docket: Use of the Term “Natural” in the Labeling of Human Food Products*, REGULATIONS.GOV (Jan. 14, 2017, 11:59 PM), <https://www.regulations.gov/document?NoD=FDA-2014-N-1207-0001>.

74. See, e.g., Winters, *Are The FDA’s New Definitions*, *supra* note 5.

75. See *id.*

76. See, e.g., K. Aleisha Fетters, *What Does ‘Natural’ Really Mean?*, U.S. NEWS & WORLD REPORT (Apr. 30, 2015, 10:46 AM), <http://health.usnews.com/health-news/health-wellness/articles/2015/04/30/what-does-natural-really-mean>.

77. See *id.*

78. See Winters, *Are The FDA’s New Definitions*, *supra* note 5.

nipulation of information will not improve our food system, and may even do harm.

For example, what will any FDA definition of “natural” allow for? Will it only account for ingredients, or will it also take process into account? What will be the role of genetically engineered ingredients? Will that definition overlap with the USDA’s definition of “organic”? Will food manufacturers be allowed to call something “natural” if it is “bad” for health (i.e., if it contains too much of an ingredient shown to be harmful if ingested excessively, like sugar)? Companies may reduce their legal fees, but the consumer will not be better off. Instead, consumers will either have to understand the specific parameters of the FDA’s definition of natural, or trust the imprimatur of government without understanding the compromises inherent in regulation.<sup>79</sup> Moreover, the FDA will spend resources that would be better spent elsewhere in creating and enforcing its regulated definition.<sup>80</sup>

Instead, the agency should target its precise objectives and write disclosures, information regulations, and an enforcement scheme accordingly. If the objective is a labeling scheme that clearly communicates to consumers what they should and should not eat, then perhaps the stoplight system proposed in the United Kingdom would be better.<sup>81</sup> Or perhaps it would be better if the Departments of Health and Human Services and Agriculture simply issued stronger recommendations in the Dietary Guidelines (a document issued every five years often riven with controversy).<sup>82</sup> Either of these could be better solutions than defining “healthy” and “natural” in ways that do not help consumers.

The regulatory solution may simply be less regulation. By making what Lisa Heinzerling calls a “noisy retreat”<sup>83</sup> from the business of defining what is “good,” the FDA may help the American consumer by forcing the necessity of understanding food without relying on labels. Or the solution may be more regulation: stoplight labels, outright bans, and stronger recommendations. Regardless, the solution is not to continue building layers of compro-

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79. *See id.*

80. *See id.*

81. *Why Food ‘Traffic-Light’ Labels Did Not Happen*, BBC NEWS (July 11, 2012), <http://www.bbc.com/news/health-18767425>.

82. *See* Roberto A. Ferdman, *We Don’t Know What to Eat*, WASH. POST: WONK-BLOG (Jan. 7, 2016), [https://www.washingtonpost.com/news/wonk/wp/2016/01/07/how-the-government-confuses-people-about-food/?utm\\_term=.21621b72f86c](https://www.washingtonpost.com/news/wonk/wp/2016/01/07/how-the-government-confuses-people-about-food/?utm_term=.21621b72f86c); *see also* Brian Secumsky, *Breaking it Down: Controversy Over the U.S. Dietary Guidelines*, HUFFINGTON POST: THE BLOG (June 23, 2016, 9:46 AM), [http://www.huffingtonpost.com/brian-secumsky/breaking-it-down-controve\\_b\\_10622814.html](http://www.huffingtonpost.com/brian-secumsky/breaking-it-down-controve_b_10622814.html).

83. Lisa Heinzerling, *The Varieties and Limits of Transparency in U.S. Food Law*, 70 FOOD & DRUG L.J. 11, 23 (2015).

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mised definitions from which the consumer is expected to glean meaningful information, as the agencies have done in the past.